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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,801

Applicant(s)

SOLAR ET AL.

Examiner

JAMES KISH

Art Unit

3737

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-43,45-70 and 76-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-43,45-70 and 76-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Previously Stated Allowable Subject Matter

The indicated allowability of claims 10-11, 22, 25-30, 36, 49, 52-57, 64-66, 76-90 and 94-97 is withdrawn in view of the newly discovered reference(s) to Stednitz et al. (US Patent No. 5,098,435), Gordon (US Patent No. 5,300,075), Grafton (US Patent Pub. No. 2001/0051807), Leclair (US Patent Pub. No. 2004/0254581), Ferrante et al. (US Patent No. 6,565,573) and Leibinger et al. (US Patent No. 5,394,457). Rejections based on the newly cited reference(s) follow.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

However, regarding the Examiner's continued use of Allen in combination with Vilsmeier with respect to claims 1-2, 5, 8-9, 12-17, 19-21, 59-61 and 67: Based on further consideration and in view of claim 21 being dependent from claim 1, it is obvious that a "bone screw shaft" as stated in claim 1 does not require rotation. Therefore, the interpretation of the Allen reference is in regard to the embodiment illustrated in Figure 1a. When Vilsmeier is combined with this embodiment of Allen, both modes of operation of the separate inventions are not deemed as inoperable, as previously argued on pages 20-21 in the Remarks dated June 22, 2007.

Any other continued use of these references in this Office Action is based on the addition of other references to teach previously objected but allowable subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-9, 11-12, 19-20, 22-24, 49, 59-64, 81-87, 91-92 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger et al.** (US Patent No. 5,394,457) – herein referred to as Leibinger - in view of **Vilsmeier** (US Patent No. 6,351,659). Leibinger discloses a fiducial marker device as illustrated in Figure 13. The device has a spherical top portion with a shaft that extends downward. At the bottom of the device is a screw that is to be driven into a tissue to be secured. As illustrated in Figure 3, there is a seat between **32** and **22**, as well as a kerf. As

illustrated in Figure 11, a plug may be removed to access the center of the device.

When the plug is removed, a substantially conical divot remains. The walls of this divot are substantially continuous toward an apex. When the plug is replaced, **42** illustrated a slot for engagement of a screwdriver (column 5, lines 6-8). The substance that is to be placed in the center of **28** may be used to image in multiple imaging modalities.

Figures 1-3 illustrate a laterally expandable distal end. The plug **40** may be considered a cap and protects the marking substance that is inside the head portion. However, there is no teaching in Leibinger for any other purpose for the hollow center except for placement of an imaggable marker. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28).

Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hollowed center of Leibinger in a similar fashion to that of Vilsmeier in order to allow a surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

Claims 32-35, 40-43, 45-48, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and further in view of **Allen**.

Leibinger in view of **Vilsmeier** is described above in the rejection of claim 1. However, no portion of a bone screw shaft that is a unitary piece of the fiducial head and that is configured to be directly secured to a bone is taught in **Leibinger**. **Allen** discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has a head which is spherical and a second portion 14 that is to be secured to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. **Allen** discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53).

Claims 68-70 and 98-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and **Allen**, and further in view of **Winters** (US Patent No. 6,464,706). **Leibinger** in view of **Vilsmeier** and **Allen** is described above in the rejection of claim 32. However, none of these references teach a guide collar that as described in the above claims. **Winters** teaches a system and associated methods for affixing soft tissue to bone. This is accomplished by inserting bone screws using a guide collar, as illustrated in Figures 7-12C. Figure 12A illustrates

using the guide collar to insert the bone screw. The guide collar is still in place in Figure 12B. Upon withdrawal of the screw as shown in 12C, the guide collar may be laterally removed. Figures 9A-C illustrates an embodiment in which the guide collar may be removed axially. Furthermore, Winters illustrates that a hole is drilled before insertion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a collar, such as that taught by Winters, in the insertion of a screw that is to be fixed to a bone, such as the marker of Leibinger in combination with Vilsmeier and Allen, in order to accurately insert the marker.

Regarding "leaving the guide collar about the fiducial marker during a time period in which the patient is to be protected against a mechanical impact to the fiducial marker," this may be interpreted as keeping the guide around the marker while it is being driven into the patient or even a split second afterward and therefore, Winters reads on these limitations.

Claims 37-39 rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and **Allen** as applied to claim 32 above, and further in view of **McCrary** et al. (US Patent No. 6,333,971). Leibinger in view of Vilsmeier and Allen is described above. However, these bone screw portions do not provide an unthreaded portion. McCrary provides a base portion of an imageable fiducial marker assembly has having both a threaded portion and an unthreaded portion. The threaded portion **32**, as illustrated in Figure 2A and 2B, has a small maximum diameter than that of the unthreaded portion, providing for a depth stop. It would have been obvious to

one having ordinary skill in the art at the time the invention was made to incorporate a narrower threaded portion to separate the fiducial marker from the surface of the patient's skull/bone.

Claim 43 rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and **Allen** as applied to claim 32 above, and further in view of either one of **Stednitz et al.** (US Patent No. 5,098,435) and **Ferrante et al.** (US Patent No. 6,565,573). **Leibinger** in view of **Vilsmeier** and **Allen** is described above in the rejection of claim 32. However, neither of these references discuss providing a self-tapping or bone cutting edge for the screw.

Stednitz et al. teaches a bone stabilizing system including a pin with an elongate solid shaft having one or more drilling teeth and self-tapping threads. A flute, best illustrated in Figure 6, provides for a cutting edge.

Ferrante et al. teaches an orthopedic screw that is preferably a self-tapping screw. As illustrated in Figures 1 and 2, flutes are created at the tip of the screw. Threads **40** of the screw cut into the bone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize bone cutting and self-tapping threading on the screw portion **Leibinger** and **Allen's** fiducial marker in order to remove the need of providing an anchor. Since the anchor is invasively placed in the patient's skull already, this removes that need and lowers the cost for the device.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and **Allen** as applied to claim 32 above, and further in view of **Franck** et al. (US Patent No. 6,273,896). Leibinger in view of Vilsmeier and Allen is described above in the rejection of claim 32. However, none of these references clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband in which to place the markers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a headband to place over the head of the bone screw/fiducials of Leibinger, Vilsmeier and Allen in order provide an alternative method of placing the markers that is less invasive for the patient..

Claims 1-2, 5, 8-9, 12-17, 19-21, 59-61 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has a head which is spherical and a second portion 14 that is to be secured to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. A trocar, or guide, is placed at the anchoring site and the marker is placed within the trocar, thereby providing a guide collar about the marker (column 8, lines 1-9). Allen discloses registering an external coordinate system B of a

robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53). While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

Claims 1-2, 5, 8-9, 13-14, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin et al.** (US Patent No. 6,327,491) – herein referred to as Franklin - in view of **Vilsmeier**. Franklin discloses a surgical fixture formed by scanning a patient. In determining specific points on the patient's surface, fiducial markers and

bone anchors are used as illustrated in Figure 1B. The screw portion is secured to an anchor, which is in turn secured to a bone. Column 4, lines 40-49 discusses a method in which the operator locates the positions of the scanning markers in the image space. As a functional equivalent to this approach, Vilsmeier teaches a reflector referencing system in which a pointer known to the system is placed in a conical divot located in the spherical head of a fiducial, as depicted in Figure 8 (column 14, lines 2-36). One advantage is that when the markers are covered with a cloth that is sized and shaped to fit over the marker heads, the conical divot is still accessible for localization. Vilsmeier also states that the shape, size and material selection for the markers is chosen to more accurately determine their position. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). The reflective coating will provide a different imaging contrast with respect to optical imaging between the head and the shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the method taught by Vilsmeier as a function equivalent to the localization method of Franklin to provide increased precision in the determination of the marker locations within the imaged space, and also to provide a system that is able to identify each of the landmarks within seconds (column 14, line 29).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** and further in view of **Overaker et al.** (US Patent No. 6,241,732). Franklin in view of Vilsmeier is described above in the rejection of claim 1. However, neither of these references teaches a hygroscopic solid material. Overaker discloses a

bioabsorbable rivet and pin fastening device that may be used for attachment of a fixation plate to bone (see Abstract). Additionally, radio-opaque markers may be added to the rivet or pin to allow imaging of the rivet and pin fastener after implantation (column 7, lines 50-52). It would have been obvious to one of ordinary skill in the art to construct the marker of Franklin in combination with Vilsmeier out of the absorbable material of Overaker because Overaker already teaches the use of the material in fiducial marker situations and would increase the utility of Franklin's marker by allowing multi-modal imaging via the contribution of liquids within the material of the marker itself (see column 7, lines 1-13 and column 7, lines 50-52).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** as applied to claim 1 above, and further in view of either one of **Stednitz et al.** (US Patent No. 5,098,435) and **Ferrante et al.** (US Patent No. 6,565,573). Franklin in view of Vilsmeier is described above in the rejection of claim 1. However, neither of these references discuss providing a self-tapping or bone cutting edge for the screw.

Stednitz et al. teaches a bone stabilizing system including a pin with an elongate solid shaft having one or more drilling teeth and self-tapping threads. A flute, best illustrated in Figure 6, provides for a cutting edge.

Ferrante et al. teaches an orthopedic screw that is preferably a self-tapping screw. As illustrated in Figures 1 and 2, flutes are created at the tip of the screw. Threads **40** of the screw cut into the bone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize bone cutting and self-tapping threading on the screw portion Franklin's fiducial marker in order to remove the need of providing an anchor. Since the anchor is invasively placed in the patient's skull already, this removes that need and lowers the cost for the device.

Claims 22, 64, 81-82, 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** and either one of **Stednitz et al.** and **Ferrante et al.**, and further in view of either one of **Grafton** (US Patent Pub. No. 2001/0051807) and **Leclair** (US Patent Pub. No. 2004/0254581). Franklin in combination with Vilsmeier and either one of Stednitz et al. and Ferrante et al. is described above in the rejection of claims 15 and 16. In combination, these references teach a spherical fiducial marker with a conical divot for localization that is capable of secured to a bone without an anchor. However, none of these references teach an expandable distal tip of the shaft.

Grafton teaches a device that is to be installed and anchored into bone. Once this is accomplished a portion at the distal end of the shaft is axially spread apart, thereby securing the device in the bone (see Abstract).

Leclair teaches a furcated orthopedic bone screw that includes a threaded portion that is cut or slotted into multiple radial segments. An outward radial force is manufactured into the distal end of the device such that once finally in the bone, the screw will not be able to pull out (see Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Franklin in combination with the aforementioned references with an expandable distal end, as taught by Grafton and Leclair, in order to properly secure the device into the bone.

Claims 23-30, 65-66 and 76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier**, and further in view of **Gordon** (US Patent No. 5,300,075). Franklin in combination with Vilsmeier is described above in the rejection of claim 1. In combination, these references teach a spherical fiducial marker with a conical divot for localization and methods of its use. However, none of these references teach a protective cap. Gordon teaches a cover for orthopedic devices that protrude from a patient's body (see Figure 11). The external housing (see Figures 9-10), which has a disk-like cap and is sized and shaped to fit over a proximal portion of the sidewalls shown in Figures 2-6, has smooth surfaces to avoid and minimize any trauma to surrounding body tissue (see Abstract). Figure 8 illustrates how the proximal end of the medical device is engaged by the cover. Figure 10 illustrates a cover that incorporates a disc-like base and circumferential peripheral cylindrical sidewalls. In Figures 2-6, a slot is shown that extends from the orifice and continues upward, finally circling outward where the sidewall meets the top. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cover, as taught by Gordon, to a protruding medical device, such as the marker taught by Franklin, in

order to avoid and minimize any trauma to surrounding body tissue (*see* Abstract) if the device is impacted by an external force.

Regarding claim 25, the protective cap described by Gordon is in contact with the surface of the patient, as can be seen in Figure 11. Therefore, it is configured to be adhered to this surface if an adhesive were applied.

Regarding claim 26, the protective cap described by Gordon covers the entirety of the medical device that is external to the patient surface, thereby including the shaft.

Regarding claim 66, the device in Figure 10 is finally placed on the device of Figure 3 and at least partially houses the fiducial marker.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** as applied above to claim 1, and further in view of **Franck** et al. (US Patent No. 6,273,896). Franklin in combination with Vilsmeier is described above in the rejection of claim 1. However, none of these references clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband in which to place the markers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a headband to place over the head of the bone screw/fiducials of Franklin and Vilsmeier in order provide an alternative method of placing the markers that is less invasive for the patient.

Claims 36 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of

either one of **Stednitz** et al. and **Ferrante** et al. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A "funnel configuration" is used to access precisely the center point of the landmark with a point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

As a teaching reference, Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches an apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen.

However, none of these references teach a threaded portion having a quarter cylindrical cutout.

Stednitz et al. teaches a bone stabilizing system including a pin with an elongate solid shaft having one or more drilling teeth and self-tapping threads. A flute, best illustrated in Figure 6.

Ferrante et al. teaches an orthopedic screw that is preferably a self-tapping screw. As illustrated in Figures 1 and 2, flutes are created at the tip of the screw.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a cutout in the threading on the screw portion, as taught by Stednitz et al. and Ferrante et al., with the system of in order to provide a cutting edge to the screw while simultaneously allowing debris to clear.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of either one of **Stednitz et al.** and **Ferrante et al.** as applied to claim 88 above, and further in view of **Gordon**. **Allen** in combination with the aforementioned references is previously described. However, none of these references teach a cover. **Gordon** teaches a cover for orthopedic devices that protrude from a patient's body (see Figure 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cover, as taught by **Gordon**, to a protruding medical device, such as the marker taught by **Franklin**, in order to avoid and minimize any trauma to surrounding body tissue (see Abstract) if the device is impacted by an external force.

Claims 49, 64, 81-85, 87 and 94-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of either one of **Grafton** and **Leclair**. **Allen** discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a

Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A "funnel configuration" is used to access precisely the center point of the landmark with a point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

As a teaching reference, Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches an apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the

screw into the bone, as taught by Allen. Furthermore, Kraus teaches a plug that will protect the insides of the divot.

However, none of these references teach laterally expanding distal ends.

Grafton teaches a device that is to be installed and anchored into bone. Once this is accomplished a portion at the distal end of the shaft is axially spread apart, thereby securing the device in the bone (see Abstract).

Leclair teaches a furcated orthopedic bone screw that includes a threaded portion that is cut or slotted into multiple radial segments. An outward radial force is manufactured into the distal end of the device such that once finally in the bone, the screw will not be able to pull out (see Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Allen in combination with the aforementioned references with an expandable distal end, as taught by Grafton and Leclair, in order to properly secure the device into the bone.

Regarding claims 95-97, Vilsmeier teaches a cover may be placed over the markers while localization is still possible. Grafton teaches that pre-drilling is a common, known practice in the art in paragraph 7. Kraus teaches a cap that may be placed into a divot of a bone screw.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, **Kraus**, and either one of **Grafton** and **Leclair** as applied to claim 81 above, and further in view of **Overaker**. **Allen** in combination with Vilsmeier, Kraus, and

either one of Grafton and Leclair is described above in the rejection of claim 81. However, none of these references teaches a hygroscopic solid material. Overaker discloses a bioabsorbable rivet and pin fastening device that may be used for attachment of a fixation plate to bone (see Abstract). Additionally, radio-opaque markers may be added to the rivet or pin to allow imaging of the rivet and pin fastener after implantation (column 7, lines 50-52). It would have been obvious to one of ordinary skill in the art to construct the marker of Franklin in combination with Vilsmeier out of the absorbable material of Overaker because Overaker already teaches the use of the material in fiducial marker situations and would increase the utility of Allen's marker by allowing multi-modal imaging via the contribution of liquids within the material of the marker itself (see column 7, lines 1-13 and column 7, lines 50-52).

Claims 52-57, 76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of **Gordon**. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the

use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A "funnel configuration" is used to access precisely the center point of the landmark with a point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

As a teaching reference, Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical

marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen.

However, none of these references teach a protective cap.

Gordon teaches a cover for orthopedic devices that protrude from a patient's body (see Figure 11). The external housing (see Figures 9-10), which has a disk-like cap and is sized and shaped to fit over a proximal portion of the sidewalls shown in Figures 2-6, has smooth surfaces to avoid and minimize any trauma to surrounding body tissue (see Abstract). Figure 8 illustrates how the proximal end of the medical device is engaged by the cover. Figure 10 illustrates a cover that incorporates a disc-like base and circumferential peripheral cylindrical sidewalls. In Figures 2-6, a slot is shown that extends from the orifice and continues upward, finally circling outward where the sidewall meets the top. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cover, as taught by Gordon, to a protruding medical device, such as the marker taught by Franklin, in order to avoid and minimize any trauma to surrounding body tissue (see Abstract) if the device is impacted by an external force.

Regarding claim 52, the protective cap described by Gordon is in contact with the surface of the patient, as can be seen in Figure 11. Therefore, it is configured to be adhered to this surface if an adhesive were applied.

Regarding claim 53, the protective cap described by Gordon covers the entirety of the medical device that is external to the patient surface, thereby including the shaft.

Claims 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier** and **Kraus**, further in view of **McCrary** et al. (US Patent No. 6,333,971). **Allen** in view of **Vilsmeier** and **Kraus** is described above. **Kraus** teaches a plug to be placed in the divot. However, these bone screw portions do not provide an unthreaded portion. **McCrary** provides a base portion of an imageable fiducial marker assembly has having both a threaded portion and an unthreaded portion. The threaded portion **32**, as illustrated in Figure 2A and 2B, has a small maximum diameter than that of the unthreaded portion, providing for a depth stop. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a narrower threaded portion to separate the fiducial marker from the surface of the patient's skull/bone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sinnott et al. (US Patent No. 6,866,666) teaches a cap that protects a protruding medical device. See Figures 29-31.

Kimura et al. (US Patent No. 4,408,372) for teaching a device that is placed over a spherical head portion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JAMES KISH** whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JMK